REMARKS

Applicant has reviewed and considered the Office Action dated November 28, 2007 and the references cited therein. In view of the following remarks, Applicant requests reconsideration and allowance of the pending claims.

Rejections under 35 U.S.C. § 103

Claims 29-32, 34-35, and 38 are rejected under 35 U.S.C. § 103(a) as unpatentable over Zdeblick (U.S. Patent 5,984,967) in view of Conston (U.S. Patent 5,456,693). Applicant traverses the rejection and insists that the Examiner's reasoning is incorrect. Applicant requests that the Examiner address, in detail, each of the points set forth below, since it is unclear why the Examiner continues to assert the Zdeblick reference. Applicant will strongly consider filing a Notice of Appeal if the Examiner continues to assert Zdeblick as a reference precluding patentability.

I. Zdeblick is Non-analogous Art

Applicant initially submits that relying on Zdeblick as a reference for a 35 U.S.C. § 103 rejection is improper. To rely on a reference under 35 U.S.C. 103, it must be analogous prior art. MPEP 2141.01(a). MPEP 2141.01(a)(iv) discusses analogy in mechanical arts. While a broad spectrum of prior art may be explored, there must be, at least, a similarity of problems between the arts:

> In a simple mechanical invention a broad spectrum of prior art must be explored and it is reasonable to permit inquiry into other areas where one of ordinary skill in the art would be aware that similar problems exist. MPEP 2141.01(a)(iv), quoting *Stevenson v. International trade Comm.*, 612 F.2d 546, 550 (CCPA 1979) (emphasis added).

Zdeblick discloses an artificial implant to be placed into the intervertebral space left after the removal of a damaged spinal disc (Zdeblick, Col. 1, ll. 12-14), and one skilled in the art of lumen occlusion would not look to the art of an implant to be placed into the intervertebral space

left after the removal of a damaged spinal disc. Specifically, the function of the elements are different, the particular fields of endeavor of the disclosed devices as a whole are different, and the problems in the fields of endeavor are different.

A. The function of the elements are different

The function of the lumen occlusion device as claimed and the function of the osteogenic fusion device of Zdeblick are different. Specifically, as claimed, a lumen occlusion device is provided to "occlude flow through the lumen." In contrast, the fusion device 10 of Zdeblick is "configured to restore the normal angular relation between adjacent vertebrae." Zdeblick, Col. 3, ll. 24-25. Zdeblick discloses:

> [T]he device 10 has an anterior end 12 and a posterior end 13, which correspond to the anatomic position of the device 10 when implanted in the intradiscal space. The conical body 11 defines a hollow interior 15 which is bounded by a body wall 16 and closed at the posterior end 13 by an end wall 17 (see FIG. 3). The hollow interior 15 of the device 10 is configured to receive autograft bone or a bone substitute material adapted to promote a solid fusion between adjacent vertebrae and across the intradiscal space. Zdeblick, Col. 5, ll. 8-17.

The function of the claimed lumen occlusion device is to occlude flow through the lumen. The function of the Zdeblick fusion device is to restore the normal angular relation between adjacent vertebrae and promote a solid fusion between adjacent vertebrae and across the intradiscal space. Zdeblick does not disclose a lumen that requires occlusion, but rather discloses the promotion of bone ingrowth. These are unrelated functions.

B. The fields of endeavor are different

The fields of endeavor of the disclosed devices are different. Specifically, Claims 29, 34, and 38 relate to a lumen occlusion device or a method of occluding a lumen. Zdeblick relates to an artificial implant to be placed into the intervertebral space and does not relate to lumen occlusion.

C. The problems in the fields of endeavor are different

As discussed in the present application:

> The technical problems of dissecting the gallbladder from the liver include stone spillage with puncture site infection, [and] liver bed bleeding . . .
>
> Whichever the technique used, the surgeon must dissect the cystic artery and duct and occlude them with metal clips or ligature before removal of the gallbladder. The cystic duct clip or ligature prevents spillage of bile from the gallbladder and its leakage from the liver. Bile leakage from the cystic duct is one of the most common problems following the cholecystectomy. The leakage could be due to incomplete duct occlusion or dislodgement of a loosely placed clip or ligature from the cystic duct stump. Further, the clip may migrate into the common bile duct, where it can induce cholesterol stones, resulting in severe abdominal and back pain. Specification, Paras. [0007]-[0008].

As previously noted, Zdeblick relates to an implant to be placed into the intervertebral space left after the removal of a damaged spinal disc. Zdeblick does not provide a solution for incomplete duct occlusion or dislodgement of a loosely placed clip or ligature resulting in leakage from the duct or lumen. Specifically, the fusion device 10 of Zdeblick includes a pair of vascularization openings 24 and 25 defined through each of the truncated side walls 22. Zdeblick, Col. 5, ll. 57-59. These openings are intended to provide a passageway for vascularization to occur between the bone implant material within the hollow interior 15 and the surrounding tissue. Zdeblick, Col. 5, ll. 62-65. The conical body 11 also defines opposite bone ingrowth slots 27, each of which are oriented at 90° to the truncated side walls 22. Zdeblick, Col. 6, ll. 5-7. The bone ingrowth slots 27 are configured to provide maximum opening for bone ingrowth, in order to ensure complete arthrodesis and a solid fusion. Zdeblick, Col. 6, ll. 13-16. That is, Zdeblick discloses a solution for the promotion of bone ingrowth and fusion. Zdeblick does not disclose a solution for duct occlusion.

II. Zdeblick is Not Properly Combinable With Conston

Assuming *arguendo* that Zdeblick is analogous art, Applicant asserts that Zdeblick is not properly combinable with Conston or any other reference relating to lumen occlusion.

A. Zdeblick does not disclose a lumen

Zdeblick simply does not disclose a body lumen. Particularly, Zdeblick does not disclose a body lumen as defined in Applicant's Specification.

The Examiner previously held a telephone interview with Nathan Witzany, a representative for Applicant, on September 6, 2007. During the interview, the Examiner asserted that Zdeblick discloses a lumen, in that the space between vertebrae, as illustrated in Figures 6, 7, and 13(a)-(d), is a lumen. Applicant emphatically asserts that the space between vertebrae is not a lumen as is recognized by one skilled in the art, and the Examiner has not provided any evidence to the contrary. Therefore, Zdeblick does not disclose a lumen occlusion device. Specifically, Zdeblick does not disclose a plug or plugging means being configured and dimensioned to occlude flow through a lumen.

The Examiner further asserted that the definition of lumen is broad enough to read on the space between vertebrae. However, Applicant, once again, directs the Examiner to paragraph [0027] of Applicant's specification, wherein Applicant has specifically defined the term "lumen":

> As used herein, "lumen" is defined as the space or cavity in the interior of a tubular structure or organ, such as an artery, vein, tube or duct, such as the bile duct. (Emphasis added).

Section 2173.01 of the MPEP states:

> A fundamental principle contained in 35 U.S.C. § 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification.

Section 2111.01(IV) reinforces the concept:

> Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (emphasis added).

Zdeblick discloses an implant to be placed into the intervertebral space left after the removal of a damaged spinal disc. The intervertebral space is not a lumen as recognized by those skilled in the art, nor is the intervertebral space a lumen as that term is defined in Applicant's Specification. If the Examiner maintains that Zdeblick discloses a lumen occlusion device, Applicant, once again, invites the Examiner to illustrate, in detail and with appropriate evidence, the manner in which the space between vertebrae fits with this definition of lumen, i.e., "the space or cavity in the interior of a tubular structure or organ, such as an artery, vein, tube or duct, such as the bile duct," provided by Applicant.

B. Zdeblick cannot be modified to expand

The osteogenic fusion device of Zdeblick cannot be modified using the teachings of Conston without destroying the function and purpose of the Zdeblick device. As stated above, Zdeblick discloses an artificial implant to be placed into the intervertebral space left after the removal of a damaged spinal disc. Zdeblick, Col. 1, ll. 12-14. The body 11 of the fusion device 10 "can be made of a medical grade stainless steel or titanium, or other suitable material having adequate strength characteristics set forth herein." Zdeblick, Col. 5, ll. 2-5. The fusion device requires strength to maintain stability of the disc interspace between adjacent vertebrae. Zdeblick, Col. 1, ll. 49-52. Zdeblick further points out that one difficulty with available fusion devices is that the devices are not structurally strong enough to support the heavy loads and bending moments applied at the most frequently fused vertebral levels. Zdeblick, Col. 2, ll. 37-47. Without such strength and stability, damage to the nerves extending along the spinal column may result. Zdeblick further provides several reasons that a preferred fusion device should mimic bone and have a modulus of elasticity that approximates that of human bone. Zdeblick, Col. 8, ll. 11-60.

In contrast, Conston discloses an embolization plug for blood vessels that is compressed so as to be longitudinally insertable into a tubular biological vessel, such as a blood vessel. Conston, Abstract. The plug then expands radially inside the vessel by absorbing fluid such as the blood and thereby providing mechanical fixation in, and occlusion of, the vessel. Conston, Abstract. Conston provides further details of the expansion:

> Typically, the plugs are compressed sufficiently so that their diameter is smaller than the lumen for ease of insertion . . . A dry, highly compressed collagen plug like this fully hydrates and expands to several times its compressed size within a short period of time upon contact with bodily fluid, thereby tightly affixing itself to a particular location within a blood vessel. Conston, Col. 2, l. 66-Col. 3, l. 9 (emphasis added).

Combining Conston with Zdeblick would produce an osteogenic fusion device for implanting into the intervertebral space that would expand to several times its compressed size. A fusion device that expands to several times its compressed size would be contrary to the purpose of the Zdeblick fusion device, which is to maintain stability of the disc interspace between adjacent vertebrae. Therefore, Conston teaches away from a combination with Zdeblick to provide a suitable osteogenic fusion device. Further, there is no reasonable expectation of success in modifying the device of Zdeblick with the teachings of Conston.

III. Zdeblick is Not Suitable for Lumen Occlusion

The reverse is also true. Zdeblick does not disclose a device that is suitable, or can be adapted, for lumen occlusion. The device disclosed in Zdeblick is a threaded device configured to be screw threaded into the end plates of adjacent vertebrae. Zdeblick, Col. 5, ll. 18-20. Furthermore, the device includes parallel truncated side walls that are preferably flat to facilitate insertion of the fusion device between the end plates of the adjacent vertebrae and provide an area between for bony fusion. Zdeblick, Col. 5, ll. 39-43. With truncated side walls, the device gives the appearance, at its end view, of an incomplete circle. Zdeblick, Col. 5, ll. 45-47. Because of these characteristics, the fusion device disclosed in Zdeblick is not conducive to lumen occlusion, particularly lumen occlusion of a lumen as defined by Applicant as "the space or cavity in the interior of a tubular structure or organ, such as an artery, vein, tube or duct, such as the bile duct." Therefore, there is no reasonable expectation of success in modifying the device of Zdeblick with the teachings of Conston.

Therefore, Claims 29-32, 34-35, and 38 are not made obvious by Zdeblick in view of Conston. Reconsideration and withdrawal of the rejection are requested.

Claims 33, 36, and 37 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Zdeblick and Conston, as applied to claims 29 and 34 above, and further in view of Wallace (U.S. Patent 6,585,754). Applicant traverses this rejection for at least the reasons provided above with respect to the combination of Zdeblick and Conston, i.e., because the base Zdeblick/Conston combination asserted by the Examiner is improper. The addition of Wallace does not cure the impropriety. Therefore, Claims 33, 36, and 37 are not made obvious by the asserted Zdeblick/Conston/Wallace combination. Reconsideration and withdrawal of the rejection are requested.

CONCLUSION

This response is being submitted on or before January 28, 2008, and no additional fees should be due. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application is in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

DORSEY & WHITNEY LLP
Customer Number 25763

Date: Jan. 23, 2008

By: 
Nathan A. Witzany, Reg. No. 60,948
(612) 492-6862